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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,537	12/11/2001	Bettina Moeckel	203973US0X	7853

22850 7590 07/29/2003

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/867,537

Applicant(s)

MOECKEL ET AL.

Examin r

Christian L Fronda

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 1-25 and 39-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## DETAILED ACTION

### *Election/Restriction*

1. Applicant's election with traverse of Group III, claims 26-38, in Paper No. 11 is acknowledged. The traversal is on the grounds that there is no reasons to support a patentable distinctness between the inventions. This is not found persuasive for reasons of record and for the reasons stated below. The invention of Group II encompasses any coryneform bacterium comprising any attenuated lysR3 gene which is expected to have a different nucleotide sequence compared to the wild type lysR3 gene of SEQ ID NO: 1 of Group I and thus would require a separate searches in the prior art. Furthermore, as stated in the previous Office Action the methods of Groups III-VI are distinct both physically and functionally, require different process steps, reagents, and parameters and produce different products; each of the processes of Groups III-VI do not require the product of Group I; and the product as claimed in Group II can be used in a materially different process of using that product such as using the coryneform bacterium of Group II in a recombinant process to make a LysR3 polypeptide which has an activity that is reduced or eliminated.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 26-38 are under consideration in this Office Action.

### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 26-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to any attenuated lysR3 gene of any nucleotide sequence and any biological source. The specification, however, only provides a single representative species encompassed by these claims: an inactivated lysR3 gene consisting of the nucleotide sequence of

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SEQ ID NO: 3. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

5. Claims 26-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing L-amino acids by culturing a transformed/recombinant bacterial cell comprising an inactivated lysR3 gene consisting of the nucleotide sequence of SEQ ID NO: 3; does not reasonably provide enablement for any other embodiment.

Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The *Wands* factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any method for producing L-amino acids by culturing any bacterial cell comprising any attenuated lysR3 gene of any nucleotide sequence and any genetic modification which results in the activity of the lysR3 protein being reduced or eliminated. The specification provides guidance and examples for a method for producing L-amino acids by culturing a transformed/recombinant bacterial cell comprising an inactivated lysR3 gene consisting of the nucleotide sequence of SEQ ID NO: 3. However, the specification does not teach the nucleotide sequence of any LysR3 gene from any biological source and any genetic modification which results in the activity of the lysR3 protein being reduced or eliminated.

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed bacterial cell comprising any attenuated lysR3 gene of any nucleotide sequence and any genetic modification which results in the activity of the lysR3 protein being reduced or eliminated for use in the production of L-amino acids is enormous and entails screening a vast number of organisms for a biological source which contains any lysR3 gene of any nucleotide sequence, performing any genetic modification which results in the activity of the lysR3 protein being reduced or eliminated, and screening for mutant lysR3 proteins which have reduced or no protein activity.

Thus, searching for the specific biological source and specific mutation is well outside the

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realm of routine experimentation and predictability in the art of success is extremely low since no information is provided by the specification regarding the specific nucleotide sequence of any lysR3 gene and any genetic modification which results in the activity of the lysR3 protein being reduced or eliminated for use in the production of L-amino acids.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific nucleotide sequence of the lysR3 gene and specific genetic modification which results in the activity of the lysR3 protein being reduced or eliminated.

6. Claims 29, 33, and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that each of the microorganisms recited in claims 29, 33, and 35 is required to practice the claimed invention. As such the recited microorganisms must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC § 112, first paragraph, may be satisfied by a deposit of each of the microorganisms recited in claims 29, 33, and 35.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicant, or a statement by an attorney of record over his/her signature and registration number, stating that the specific microorganism has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809 and MPEP 2402-2411.05, the applicant may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his/her signature and registration number, showing that:

- (1) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (2) all restriction upon availability to the public will be irrevocably removed upon granting of the patent;
- (3) the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (4) the deposit will be replaced if it should ever become inviable.

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***Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 26-38 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: isolating and recovering the produced L-amino acid.

9. Claims 26-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 26, the phrase "attenuated lysR3 gene" renders the claim vague and indefinite since the meaning of the phrase is not known and the specific genetic mutation involved in creating the "attenuated lysR3 gene" is not known and not recited in the claim. Claims 27-38 are also rejected because they do not correct the defect of claim 26.

In claims 36 and 38, the phrase "one gene whose expression is enhanced" renders the claim vague and indefinite since the meaning of the phrase is not known and the specific genetic mutation involved in creating the "one gene whose expression is enhanced" is not known and not recited in the claim.


In claim 37, the phrase "one gene whose expression is attenuated" renders the claim vague and indefinite since the meaning of the phrase is not known and the specific genetic mutation involved in creating the "one gene whose expression is attenuated" is not known and not recited in the claim.

***Conclusion***

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

  
PONNATHAPURA ACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600